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13. ABSTRACT (Maximum 200) This grant provides partial core support for the Institute of Laboratory Animal Resources (ILAR), which is a component of the Commission on Life Sciences (CLS), one of the principal operating units of the National Academy of Sciences (Academy). The Academy operates as a private, non-profit institution charged with providing advice to agencies of the federal government on matters of science and technology. ILAR provides information as to selection, care, and use of biologicals and animals used in research, testing, and education. Two reports were published in 1996: ILAR's best know report, the Guide for the Care and Use of Laboratory Animals (Guide); and an update of the Rodent report of the Laboratory Animal Management Series. In additional, the report Occupational Health and Safety in the Care and Use of Research Animals was completed and will be published in 1997. Oversight for the work of ILAR is provided by ILAR Council, a standing committee of 14 scientists, veterinarians, and ethicists, which meets three times each year to review all aspects of ILAR's program and develop new initiatives. ILAR has two types of programs—core and special projects. This grant primarily supports the core program, consisting of the meetings of Council, ILAR Journal, the Animal Models and Genetic Stock Information Program, and international activities. Partial support is also provided for the development of special projects and convening of workshops.			
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FOREWORD

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In conducting research using animals, the investigator(s) adhered to the "Guide for the Care and Use of Laboratory Animals," prepared by the Committee on Care and use of Laboratory Animals of the Institute of Laboratory Resources, National Research Council (NIH Publication No. 86-23, Revised 1985).

For the protection of human subjects, the investigator(s) adhered to policies of applicable Federal Law 45 CFR 46.

.. In conducting research utilizing recombinant DNA technology, the investigator(s) adhered to current guidelines promulgated by the National Institutes of Health.

In the conduct of research utilizing recombinant DNA, the investigator(s) adhered to the NIH Guidelines for Research Involving Recombinant DNA Molecules.

In the conduct of research involving hazardous organisms, the investigator(s) adhered to the CDC-NIH Guide for Biosafety in Microbiological and Biomedical Laboratories.

Thomas J. Clegg 1/30/07
PI - Signature Date

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1996 ANNUAL REPORT
INSTITUTE OF LABORATORY ANIMAL RESOURCES
NATIONAL RESEARCH COUNCIL
GRANT NUMBER DAMD 17-93-J-3016

INTRODUCTION

This grant provides partial core support for the Institute of Laboratory Animal Resources (ILAR), which is a component of the Commission on Life Sciences (CLS), one of the principal operating units of the National Academy of Sciences (Academy). Under an 1863 congressional charter, the Academy operates as a private, non-profit institution charged with providing advice to agencies of the federal government on matters of science and technology. Since 1952, ILAR has served this role in regard to the selection, care, and use of animals and biologicals used in research, testing, and education. A new edition of ILAR's best known report, *Guide for the Care and Use of Laboratory Animals* (*Guide*), was published this year. Another Laboratory Animal Management report on Rodents was also published. The report *Occupational Safety and Health in the Care and Use of Animals* was completed this year and will be published in early 1997. Oversight for the work of ILAR is provided by ILAR Council and the CLS.

ILAR Council is a standing committee of 14 scientists, veterinarians, and ethicists, which meets three times each year to review all aspects of ILAR's program and develop new initiatives. John VandeBerg, Scientific Director, Southwest Foundation for Biomedical Research, is the chairman of Council (see Appendix 1: ILAR Committee Rosters).

ILAR's work follows procedures prescribed in the charter of the Academy and operating procedures of the National Research Council (NRC), the administrative arm of the Academy. When federal agencies request the advice of the NRC, a series of events is set into motion that typically leads to published recommendations on the desired topic. The strength of this process is achieved by selecting and appointing a balanced committee of experts that produces a report in accordance with NRC operating procedures. Separately appointed committees of experts provide anonymous review of each report. Staff supports and enables this process behind the scenes, which is a component of ILAR's core programs.

BODY

ILAR has two types of programs: core and special projects. The core program includes the work involved with supporting ILAR's advisory council, maintaining ILAR's ongoing programs, and initiating and prioritizing ILAR's special projects. This grant supports the core program. Special projects are those accomplished by NRC-appointed volunteers who serve on NRC-appointed committees. All ILAR committees work under the auspices of the NRC, and are overseen by the CLS. Committee reports, which usually

take 18 to 36 months to complete, are submitted for independent peer review. Reports are normally published by the National Academy Press. See Appendix 1 for ILAR committee rosters.

I. Core Activities

A. ILAR Council. ILAR council met three times in 1996 to review ongoing work and plan new activities: March 7-8 at the National Academy of Sciences Building, Washington, D.C.; July 8-9 at the Arnold and Mabel Beckman Center, Irvine, California; and October 16-18 at the National Academy Sciences Building, Washington, D.C. The Beckman center is a study site of the Academy and enables greater participation of west coast members. ILAR Council works under the general guidance of ILAR's Mission Statement:

The Institute of Laboratory Animal Resources (ILAR) develops guidelines and disseminates information on the scientific, technological, and ethical use of animals and related biological resources in research, testing, and education. ILAR promotes high-quality, humane care of animals and the appropriate use of animals and alternatives. ILAR functions within the mission of the National Academy of Sciences as an advisor to the federal government, the biomedical research community, and the public.

The primary responsibility of Council is to review all ongoing activities. This is the main focus of Council meetings and innumerable conference calls between meetings.

Council reviewed the progress of the following current committees during 1996. See below for project descriptions.

Occupational Health and Safety in Care and Use of Research Animals

Psychological Well-being of Nonhuman Primates

The Long-Term Care of Chimpanzees in Biomedical and Behavioral Research

Council initiated or reviewed the activities of the following new projects during 1996. See below for project description.

New and Emerging Models in Biomedical Research

Cost of Animal Research (PIF workshop)

In addition to the ongoing projects and new initiatives (see II. Special Projects), Council concentrated on the activities of the following three subcommittees of core activities.

B. ILAR Journal. With oversight and guidance by the ILAR Editorial Board, *ILAR News* was reformatted, and expanded, and renamed *ILAR Journal* in 1995. *ILAR Journal*, a quarterly, peer-reviewed publication provides thoughtful and timely information for those who use, care for, and oversee the use of laboratory animals. The audience of *ILAR Journal* includes more than 3,500 investigators in biomedical and related research, institutional officials for research, veterinarians, and members of animal care and use committees. The *ILAR Journal* Editorial Board, a subcommittee of the ILAR Council, plans each issue around a chosen theme and carefully solicits authors to best present a balanced view of the topic which is then peer reviewed.

Contents will include up-to-date articles on appropriate animal models, strategies to reduce or avoid painful procedures in animals, and other sensitive issues; articles of interest to institutional animal care and use committees; articles or commentary concerning international or emerging issues; and, when appropriate, reports of ILAR committees. Invited comments on published manuscripts and unsolicited letters to the editor will be published to provide a forum for scientists to exchange information and express opinions. The contents of volumes published in 1996 are provided in Appendix II.

C. Animal Models and Genetic Stocks Information Program (AMGS). Some of the most critical information needed by scientists is often the most difficult to obtain, including information on the most appropriate model for the proposed research and, if the model is an animal, to find sources of the model and information on appropriate care. For 45 years, ILAR has conducted a program to provide such information. That program, called the Animal Models and Genetic Stocks Information Program, offers assistance in locating sources of animals, selecting appropriate animal models, using standardized nomenclature, understanding the importance of the use of animals in biomedical and behavioral research and testing, and interpreting guidelines for the humane care and use of animals. It includes two databases: one (called Animals for Research, AFR) contains commercially available and investigator-held colonies of animals for research; the other is a registry of codes used with standardized nomenclature of rodents and rabbits to identify institutions that maintain breeding colonies. During 1996 ILAR staff documented over 1,300 responds to questions and responded to many more by telephone, fax, and e-mail. The databases have been incorporated into ILAR's World Wide Web (WWW) home page and will soon be available to investigators world-wide. It is on the NRC test server now.

D. International Activities. The International Subcommittee of ILAR Council met three times in 1996, preceding each meeting of Council. ILAR's international activities mission statement for the Western Hemisphere is:

As a national resource for science-based policy development, ILAR will seek to establish a joint partnership with Canada (linked through NAFTA) for the dissemination of educational and training materials in Mexico. The goal of this activity is to assist in the development of regional self-reliance in health research. Mexico will serve as a model for follow-on activities in Central and South America and the Caribbean.

For Asia and the Pacific Rim:

ILAR seeks to further the relationships with Japan through the U.S.-Japan Non-Energy Agreement and with the International Council for Laboratory Animals Science for the further development and refinement of animal models, the sharing of information and facilities, and the education and training of young scientists in development countries.

For Europe:

ILAR seeks to work with European countries to assist with the harmonization of nontariff trade barriers, regulations, and the collection and transfer of biological materials.

In order to facilitate these liaisons, ILAR interacts with numerous organizations and agencies in the United States and foreign countries. Among these are the NRC/CLS joint programs with the Mexican Academy of Sciences, and the Pan American Health Organization, Fogarty International Center at NIH, Department of State, Centers for Disease Control and Prevention, Interagency Research Animal Committee, U.S. Agency for International Development, Canadian Council on Animal Care, Agriculture Canada, and various Mexican department of animal health and agriculture. In addition, ILAR maintains close contract with U.S. scientific societies, pharmaceutical companies, biomedical investigators, veterinarians, and administrators. This network serves to alert ILAR of existing or anticipated international problems affecting biomedical and biological research and biodiversity and to enable ILAR to better understand the broad needs of U.S. science in interacting with foreign organizations.

One of the goals of ILAR's international activity is to facilitate the impact of NAFTA for the benefit of trade affecting scientific exchange. The ILAR Council invited representatives from Canada and Mexico to an organizational meeting of NAFTA countries to discuss biomedical issues. Following a March 1, 1995 workshop in which key participants from NAFTA countries met and discuss relevant multilateral issues affecting biomedical and agricultural issues in their country. Second workshop was held on October 16, 1996. ILAR Council met with representatives of Canada and Mexico as part of the ongoing dialogue with NAFTA members for the purpose of a better understanding of key issues that might impact the exchange of biological and pharmaceutical products and animals.

A key component of the international activities is ILAR's involvement as the U.S. national member of the International Council for Laboratory Animal Science (ICLAS). ICLAS is a non-governmental organization for international cooperation in laboratory animal science. This membership affords a conduit for U.S. investigators to develop and conduct an active international program in laboratory animal science. A former Council chairman (Steven Pakes) was elected in 1995 as Secretary General of the ICLAS General Assembly, and a three-member subcommittee of the ILAR Council functions as the U.S. national committee for ICLAS. Together they provide federal agencies and other interested organizations with information and advice on international issues and problems in laboratory animal science.

II. Special Projects

In addition to those areas discussed under I. Core Projects, this grant provides support for some of the activities of ILAR's Special Projects, the second primary focus of ILAR's activity. These projects normally evolve in one of two ways. The first way is when ILAR Council or another NRC component believes a workshop is needed to explore a specific topic to determine whether more in-depth study should be undertaken.

The second way in which special projects evolve is through the recommendation of a workshop or through direct request of an agency or Congress. Most NRC special projects are conducted in order to provide advice to one or more federal agencies, and such is the case for the following ILAR's projects: Revision of the Guide for Care and Use of Laboratory Animals (Guide); Occupational Health and Safety in Care and Use of Research Animals; Psychological Well-being of Nonhuman Primates; The Long-Term Care of Chimpanzees in Biomedical and Behavioral Research; New and Emerging Models for Biomedical Research and the Cost of Animal Research. The following is a list of these special projects, including a summary of accomplishments during 1996 in each, and plans for the future.

A. Revision of the *Guide for Care and Use of Laboratory Animals (Guide)*. The seventh edition of the *Guide* began in 1993. The report was completed in 1995 and published in 1996. Translation and dissemination of the *Guide* in foreign countries is being pursued, as well as placing the translations on the ILAR home page (see Appendix 1: ILAR Committee Rosters).

B. Laboratory Animal Management Series. As companions to the *Guide*, ILAR extensively revised two species-specific reports in the *Laboratory Animal Management* series. *Dogs: Laboratory Animal Management Series* was published in 1994. *Rodents: Laboratory Animal Management Series* was published in 1996. Revising this report was especially important because the USDA anticipates adding rodents of the genera *Mus* and *Rattus* to the animals whose use is regulated. As a result of the report, ICLAS established a committee on quality control with a goal of achieving international standards for genetic and microbiological quality control of laboratory rodents (see Appendix 1: ILAR Committee Rosters).

C. Occupational Health and Safety in the Care and Use of Research Animals. This committee completed its report in 1996. The report is being published by the National Academy Press and will be available in early 1997. A committee comprehensively reviewed safety and health concerns associated with animal facilities and recommended procedures by which federal laboratories and large and small institutions can appropriately address these concerns. The report will, for the first time, provide institutions conducting research with detailed recommendations for the components to include in an occupational health and safety program (see Appendix 1: ILAR Committee Rosters).

D. Psychological Well-being of Nonhuman Primates. This report is currently in external review and is expected to be completed in spring 1997. The report reviews existing laws and policies, reviews current operational procedures and constraints, and provides basic guidance to assist institutions and inspectors in developing and assessing institutional programs for the psychological well-being of nonhuman primates in research environments. Because of the nature of the subject, it is neither possible nor desirable to develop specific guidelines. Rather, this study will provide one of many possible starting points from which programs and dialogue can develop. The committee roster is attached (see Appendix 1: ILAR Committee Rosters).

E. The Long-Term Care of Chimpanzees in Biomedical and Behavioral Research.

Due to their close phylogenetic relationship to humans, chimpanzee models have led to better understanding of human and animal diseases, development of important new vaccines, and behavioral knowledge essential to the conservation of the species. With funding from NIH a committee has been established to prepare a report that provides recommendations for the long-term care and appropriate use of chimpanzees that have served as valuable models in biomedical and behavioral research. The study will also assess the importance of chimpanzees for future research and testing and to make recommendations on how best to manage current populations to meet critical needs. The committee held all of its 5 meetings in 1996: June 18-19 in Washington, D.C., July 25-26 in San Antonio, August 15-16 in Madison, WI, October 7-8 in Irvine, CA, and December 7-8 in Irvine. The report will shortly undergo editing and enter the review process. Completion is expected in the spring of 1997 (see Appendix 1: ILAR Committee Rosters).

F. The Role of New and Emerging Models in Biomedical and Behavioral Research.

Funding was received in 1996 from NIH to convene a panel of experts to prepare a report that will examine opportunities and priorities for animal-based, scientifically driven research in the Comparative Medicine Program at the National Center for Research Resources. The workshop to be held in Spring 1997 will use case studies to discuss criteria and action needed to identify useful new animal models for biomedical and behavioral research; the tools, technologies, and resources needed to develop and support them; and the barriers that can prevent or delay their development and support.

G. The Cost of Animal Research. Many life scientists believe that the high and rising costs associated with animal research are adversely affecting research grants and unnecessarily limiting the pace of research. The basis for this concern will be discussed at a workshop planned for spring 1997. It is hoped that the workshop would be a prelude to a full-fledged study which would explore the true costs of biological research, including animal cost (actual and indirect), administrative costs (oversight committees, paper work, and regulatory requirements including permitting and transporting costs, Office of Management and Budget (OMB) Circular A-21 (which prohibits indirect costs for animal colonies), and other issues. By focusing on the costs associated with animal-based research, such a study would assist in the reduction of unnecessary administrative costs and would provide a clearer understanding to investigators of the basis for per diem costs.

H. Workshop Series on Access to Biologicals for Research and Education. ILAR has received partial funding for a working series looking at the permitting process. Biological research increasingly requires the collection and movement of sera, cells, and other specimens as well as whole plants and animals from one country to another or from the field to a laboratory. Collection, transport and disposition of such material is closely regulated to protect both the species and its ecology and the public health. The resulting rules and regulations have become exceedingly complex. A workshop held in March 1994 concluded that further workshops would be helpful in understanding and finding ways to deal with the permitting process. The council continues to be interested in seeking harmonization among the various permitting agencies in the US. The workshops will be held once adequate funding is obtained.

I. Transgenic Animals: Benefits and Risks. ILAR has received partial funding for a project that would produce a short report for the public on the benefits, of, risks from, and ethical issues concerning genetically altered organisms. Council remains interested in seeing this project initiated.

CONCLUSIONS AND FUTURE DIRECTIONS

- ILAR Council met three times.
- Two reports were published: *Guide for Care and Use of Laboratory Animals (Guide); Rodents: Laboratory Animal Management Series.*
- One report was completed: *Occupational Safety and Health in the Care and Use of Animals.*
- Five meetings of the Committee on Long-Term Care of Chimpanzees were held and a first version of the report completed.
- A NAFTA/GATT workshop was held with representatives of Canada and Mexico.
- Planning began for two workshops: on New and Emerging Models in Biomedical Research.; and on the Cost of Animals.
- The Animals Models and Genetic Stocks and the international list of laboratory codes were placed on the Academy's test server.
- The Managing Editor of *ILAR Journal* will continue to work with the Council-appointed *ILAR Journal* Editorial Board to solicit manuscripts and invite commentary, arrange for peer review of the articles, and publish the journal quarterly.
- ILAR Council remains interested in obtaining further funding in order to hold a Workshop Series on Access to Biologicals for Research and Education and to begin projects on Transgenic Organisms and on the Cost of Animal Research.

**1996 Annual Report
Institute of Laboratory Animal Resources
National Research Council
Grant Number DAMD 17-93-J-3016**

**APPENDIX 1
ILAR COMMITTEE ROSTERS**

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**1996 Annual Report
Institute of Laboratory Animal Resources
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